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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,512	03/16/2006	Ben Hankamer	012930-000026	7935

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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/562,512

Applicant(s)

HANKAMER ET AL.

Examiner

Mohammad Meah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28, 37 and 45 is/are allowed.
- 6) ☒ Claim(s) 30-36 and 38-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/5/07, 3/1/07, 12/28/05</u> | 6) <input type="checkbox"/> Other: _____ |

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Election/Restriction

During preliminary amendment of this application, the applicant, on date 6/1/07 cancel claims 1-22 and 29 and elected without traverse Group V (claim 28) and added new claims 30-45 for examination. Therefore Claims 28 and 30-45 will be examined here.

Priority

Acknowledgement is made of applicant's PCT priority date based on application filing date of 7/7/2004, # PCT/AU04/00913 and foreign priority filing date 7/7/2004 # Australia 2003903453.

Claim Objections

Claim 37 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 28. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections

35 U.S.C 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 - the recitation "illuminated conditions" is confusing and vague as it is unclear what "illuminated conditions" means.

Claims 30 and 38 - the recitation "HydA" is confusing as it is unclear whether it refers to specific hydrogenase or not.

Claims 30 and 38 - the recitation "moc1" is confusing as it is unclear whether "moc1" is from specific organism or not.

35 U.S.C 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 30-36, 38-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to any mutant alga from any source or any *chlorococcales* and *Volvocales* types of algae or cell culture comprising said mutant alga expressing any *HydA* hydrogenase having a mutation that results in reduced activity of any mitochondrial transcription factor comprising any Moc1 so that said mutant alga produce more hydrogen than wild-type alga. The genus of alga or cell culture comprising said mutant alga expressing any *HydA* hydrogenase having any mutation which results in reduced activity of any mitochondrial transcription factor comprising any Moc1 is a large variable genus containing many algae from many sources. Specification neither teaches the structures of all algae nor teaches how all algae express any hydrogenase and are mutated to reduce activity of any mitochondrial transcription factor comprising any Moc1. The specification teaches only one mutant alga (as recited in claim 37 or 45). Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 30-36, 38-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling mutant alga *chlamydomonas reihardtii stm6*, does not reasonably provide enablement for any mutant alga from any source or any *chlorococcales* and *Volvocales* types of algae or cell culture comprising said mutant alga expressing any *HydA* hydrogenase and having any mutation to reduce activity of any mitochondrial transcription factor comprising any *Moc1* so that said mutant alga produce more hydrogen than wild-type alga.. The claims broadly recite any mutant alga from any source or any *chlorococcales* and *Volvocales* types of algae or cell culture comprising said mutant alga expressing any *HydA* hydrogenase and having any mutation to reduce activity of any mitochondrial transcription factor comprising any *Moc1* so that said mutant alga produce more hydrogen than wild-type alga. There are many means of making mutant algae such as mutations of the gene itself, addition of inhibitors, modification of endogenous modulators, mutating, mutant alga from any source or any *chlorococcales* and *Volvocales* types of algae or cell culture comprising said mutant alga can express any *HydA* hydrogenase and having a mutation to reduce activity of any mitochondrial transcription factor comprising any *Moc1* so that said mutant alga produce more hydrogen than wild-type alga..

Claims 30-36, 38-44 are so broad as to include any mutant alga from any source or any *chlorococcales* and *Volvocales* types of algae or cell culture

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comprising said mutant alga expressing any *HydA* hydrogenase and having a mutation to reduce activity of any mitochondrial transcription factor comprising any Moc1 so that said mutant alga produce more hydrogen than wild-type alga.. The specification fails to describe how to make **any** algae expressing any *HydA* hydrogenase and how any algae can be mutated to reduce activity of mitochondrial transcription factor comprising any Moc1. The class of algae and *HydA* hydrogenase and mitochondrial transcription factor comprising any Moc1 is a large variable genus having any structure. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number way of mutating any algae so that it shows reduce activity of mitochondrial transcription factor comprising any Moc1 and expressing any *HydA* hydrogenase. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to only one mutant alga *chlamydomonas reinhardtii* *stm6*,.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as

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encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. Furthermore, there are many means of controlling gene function such as mutations of the gene itself, modification of endogenous modulators, mutating individual nucleic acid, etc. It is not routine in the art to control a gene by any means to obtain desired outcome. Without knowing the structural feature of the protein it encodes, controlling the gene by any means (i.e., such as modification of the gene by mutations) to obtain desired function is unpredictable. Production of hydrogen involves a large number of different enzymes. Controlling a few genes without affecting other genes that involve in the hydrogen synthesis is difficult. The specification does not support the broad scope of the claims which encompass any mutant alga from any source or any *chlorococcales* and *Volvocales* types of algae or cell culture comprising said mutant alga expressing any *HydA* hydrogenase and having a mutation to reduce activity of any mitochondrial transcription factor comprising any *Moc1* because the specification does not establish: (A) regions of the protein structure of *HydA* and *Moc1* genes which should be modified to increase hydrogen synthesis activity and/or how to control *HydA* and *Moc1* by any means to obtain desired function (B) the general tolerance of *HydA* and *Moc1* to modification and extent of such tolerance

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towards controlling the gene with any means; (C) a rational and predictable scheme for modifying any *HydA* and *Moc1* with an expectation of obtaining the desired biological function; and / or controlling them by any means towards such biological function (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any mutant alga from any source or any *chlorococcales* and *Volvocales* types of algae or cell culture comprising said mutant alga expressing any *HydA* hydrogenase and having a mutation to reduce activity of any mitochondrial transcription factor comprising any *Moc1*. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making modified alga from any source or any *chlorococcales* and *Volvocales* types of algae or cell culture comprising said mutant mitochondrial transcription factor comprising any *Moc1* is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

Claims 30-36,38-44 are rejected and claims 28, 37 and 45 are allowable.

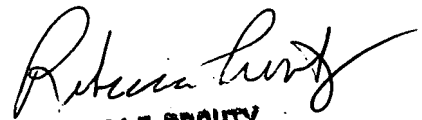
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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